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Total No. of Questions: 10

# B.Pharma (2011 to 2016) (Sem.-8) PHARMACEUTICS-IX (DOSAGE FORM DESIGN) Subject Code: BPHM-801

Time: 3 Hrs. Max. Marks: 80

# INSTRUCTIONS TO CANDIDATES:

- SECTION-A is COMPULSORY consisting of FIFTEEN questions carrying TWO marks each.
- SECTION-B contains FIVE questions carrying FIVE marks each and students have to attempt any FOUR questions.
- SECTION-C contains FOUR questions carrying TEN marks each and students have to attempt any THREE questions.

# SECTION-A

# Answer briefly :

- a) What is meant by pharmaceutic equivalent?
- b) What is retrospective validation?
- c) What is racemization? Give two examples.
- d) Give two examples of BCS III drugs.
- e) What should be the disintegration time of dispersible tablets IP?
- Mention the stability testing conditions for Zone II.
- g) Propyl gallate and EDTA are used for which purposes?
- h) Give examples of two drugs that are formulated in micronized state.
- Mention the methods that can be used for enhancing the solubility of poorly water soluble drugs.
- j) Differentiate between controlled and delayed release.

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- k) Why is DOSS added to dissolution media?
- What is absolute availability?
- m) What is the difference between excretion and elimination?
- n) Enumerate different types of particle diameters.
- o) What is meant by sedimentation volume of suspensions?

# SECTION-B

- Write briefly about the impact of particle size and shape in influencing the stability of suspensions.
- Giving examples of prodrugs that have proven advantage over their parent molecular forms, explain the reasons thereof.
- What is BCS? Briefly describe the different classes of drugs giving examples.
- Give examples of drugs that are highly prone to oxidation and suggest methods to make them stable.
- Write a brief note on Quality Audit.

#### SECTION-C

- Enlist the physicochemical properties of drugs that are evaluated during preformulation phase. Discuss the importance of particle size, shape and density in influencing dosage form development.
- What is validation? Explain the different types of validations and mention the conditions for which they are carried out.
- Discuss the key features of a Bioequivalence trial. Discuss the ICH requirements for establishing Bioequivalence of drug products.
- Discuss the IVIVC requirements according to ICH guidelines.

NOTE: Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

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